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FINGERTIP CONFORMING FLUID EXPRESSION CAP

BACKGROUND

The present invention generally relates to bodily fluid sampling devices and more specifically, but not exclusively, to a bodily fluid sampling device with an expression cap that allows a more complete contact with the skin around an incision.

A variety of devices have been developed to sample bodily fluids. These devices may use a needle to prick a finger or other means of forming an incision in the body. The devices are commonly used on the finger because the finger contains a high density of capillaries full of blood. Other devices are used to take bodily fluid samples from alternate site testing (AST) locations such as the forearm. These AST locations commonly make it less painful for the user; however, the amount of bodily fluid bled from an incision is commonly lower. Typically, the devices are hand held and are placed against the finger or some other body part. An incision is formed and bodily fluid from the incision is drawn onto a test strip or some other testing device. For example, the test strip can be used to determine the levels of selected analytes in the bodily fluid, such the blood glucose levels.

Sometimes the amount of blood naturally bled from the incision is insufficient for testing purposes, and additional fluid needs to be expressed from the incision before the fluid can be analyzed. Bodily fluid can be expressed from incisions in a number of manners, such as with a vacuum and/or mechanically. In one form, a sampling device with a hollow, cylindrically shaped expression member is pressed around an incision in a finger or some other body part. By pressing the expression member around the incision, the pressure of the bodily fluid in the skin inside the expression member increases so that additional fluid is

forced out of the incision. One problem associated with this expression member design is that the contact surface of the expression member is flat, whereas most body parts are not. This flat type of expression member design in turn leads to uneven pressure being applied around the incision, which can block blood flow to the incision, while at the same time allow blood to flow away from the incision site. For example, when a flat expression member is pressed against a finger, uneven pressure is applied around the incision site. Specifically, the expression member blocks the flow of blood in the arteries along the finger, while at the same time allows blood to escape from the sides of the finger. This uneven contact between the expression member and the skin can lead to the user having to attempt to express the fluid over again, and may even require the user to lance the skin again.

Thus, the need remains for further contributions in this area of technology.

SUMMARY

In one aspect of the present invention, a bodily fluid sampling device includes an incision forming device to form an incision in a finger and an expression cap. The expression cap has an opening through which the incision forming device forms an incision and an expression surface to express fluid from the incision. The expression surface has at least two opposing compression surfaces with a negative sigmoidal shape to enhance expression of body fluid from the incision. The expression cap defines a relief notch between the compression surfaces, and the relief notch is sized to receive the finger, or some other body part, to permit the compression surfaces to first contact the finger when the expression surface is pressed against the finger.

Another aspect concerns, a bodily fluid sampling device that includes means for forming an incision in a body part and an expression cap. The expression cap defines an opening through which the means for forming the incision forms the incision. The expression cap has an expression surface, and the expression surface defines a relief notch. The expression surface is shaped to apply a generally even force against the body part when expressing body fluid from the incision.

A further aspect concerns a technique for expressing body fluid. A sampling device has an expression surface with at least two opposing compression surfaces that have a negative sigmoidal shape and a relief notch defined between the compression surfaces that is shaped to generally conform to a body part. The expression surface is placed against the body part with at least a portion of the body part received in the relief notch. An incision is formed in the body part with the sampling device, and the body fluid is expressed from the incision by exerting pressure between the body part and the expression surface.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of an expression cap of a bodily fluid sampling device according to one embodiment of the present invention.

FIG. 2 is a top plan view of the FIG. 1 expression cap.

FIG. 2A is a top plan of an alternate embodiment of an expression cap.

FIG. 3 is a cross-sectional view of the FIG. 1 expression cap taken along line 3-3 in FIG. 2.

FIG. 4 is a cross-sectional view of the tip of the FIG. 1 expression cap along line 4-4 in FIG. 3.

FIG. 5 is an exploded view of a bodily fluid sampling device that incorporates the FIG. 1 expression cap.

FIG. 6 is a cross-sectional view of the FIG. 5 device.

FIG. 7 is a cross-sectional view of the FIG. 5 device during lancing of a finger.

FIG. 8 is a cross-sectional view of the FIG. 5 device expressing fluid from the finger.

FIG. 9 is a side view of the expression cap of FIG. 1.

DESCRIPTION OF SELECTED EMBODIMENTS

For the purposes of promoting an understanding of the principles of the invention, reference will now be made to the embodiments illustrated in the drawings and specific language will be used to describe the same. It will nevertheless be understood that no limitation of the scope of the invention is thereby intended. Any alterations, modifications, and further applications of the principles of the present invention as illustrated are contemplated as would normally occur to one skilled in the art to which the invention relates.

A bodily fluid sampling device according to one embodiment includes an expression cap having an expression surface with a relief area to allow an improved contact between the expression surface and the body area from which bodily fluid is to be sampled. The relief area centers the contact area around the incision formed in the body part. The combination of a concave expression surface with the relief area creates a more even compressive force to help express the fluid out of the body part contacting the expression surface.

An expression cap 20 according to one embodiment, among others, is illustrated in FIGS. 1, 2, 3, and 4. The expression cap 20 is configured to express fluid from the area surrounding an incision. Referring to FIG. 1, the expression cap 20 includes an expression portion 21 that is configured to contact the skin around an incision, a support portion 22 to support the expression portion 21 when a body part is pressed against the expression portion 21, and a connection portion 23 that allows the expression cap 20 to be connected to a sampling device. The expression cap 20 may be composed of various materials including, but not limited to, plastic, rubber, metal, a composite material, a combination thereof, or other materials commonly known to one skilled in the art. In one embodiment, the expression portion 21 is able to be detached from the support portion 22. Conversely, it is contemplated that the expression portion 21 in other embodiments can be permanently affixed to the support portion 22. The expression portion 21 generally includes an expression surface 24

configured to contact the skin surrounding an incision and a lancet opening 25 adapted to allow a lancet to pass through the expression portion 21 during lancing. The lancet opening 25 is illustrated as being circular. Nonetheless, it should be understood that the lancet opening 25 can be shaped differently in other embodiments. For example, the lancet opening 25 can be rectangular, square and/or an irregularly shaped in other embodiments.

As illustrated, the expression surface 24 has relief notches 26 that improve the contact with the skin surrounding the expression surface 24. In the illustrated embodiment, the relief notches 26 are shaped to generally conform to the shape of a finger, but it should be appreciated that the notches 26 can be shaped to conform to other body parts, such as the forearm. By generally conforming to the shape of the finger, the relief notches 26 permit a generally even pressure to be applied against the skin around the incision, which in turn increases the amount of fluid expressed from an incision. In the illustrated embodiment, the expression surface 24 surrounding the notches 26 has a negative sigmoid shape because it was discovered that the negative sigmoid shape of the expression surface 24 in conjunction with the relief notches 26 was particularly effective in expressing fluid. The negative sigmoid shape of the expression surface 24 promotes fluid flow from the sides of the finger towards the incision. In one embodiment, the relief notches 26 can be configured to not cut off the circulatory flow of blood in the arteries along the finger, thereby permitting an even greater blood flow from the incision.

The support portion 22 includes a depression 27 for gripping the expression cap 20. In this embodiment, the depression 27 is depicted having a parabolic shape, but it is envisioned that the depression can be shaped differently in other embodiments. In one form, the depression 27 is shaped to conform to human fingers for easy grasping of the expression cap 20 during insertion or removal of the expression cap 20 from a sampling device. As illustrated in FIG. 1, the support portion 22 has a larger diameter than the connection portion

23. The larger diameter of the support portion 22 catches the expression cap 20 when the connection portion 23 is inserted into a sampling device.

Referring now to FIG. 2, the expression portion 21 is illustrated as having an overall cylindrical shape. However, it should be understood that the shape of the expression portion 21 can vary in other embodiments. For example, the expression portion 21 in other embodiments can be rectangular in shape. The expression portion 21 includes a beveled edge 32 that runs along the circumference of the expression portion 21. As shown, the relief notches 26 include a first relief notch 33 and a second relief notch 34. The relief notches 26 are aligned directly across from one another along the expression surface 24 so as to coincide with a finger laying across the notches 26. In alternative embodiments, the first relief notch 33 and the second relief notch 34 can be placed in different locations upon expression surface 24. In the illustrated embodiment, the relief notches 26 have a concave or curved shape so as to coincide with the shape of a finger. However, it should be appreciated that the relief notches 26 can be shaped and sized differently so as to coincide with the shape of other body parts, such as the forearm. Moreover, it is contemplated that the expression surface 24 can include more or less relief notches 26 than is illustrated.

With continued reference to FIG. 2, the expression surface 24 further has opposing first 37 and second 38 compression surfaces for applying a compressive force against the skin surrounding the incision during expression of fluid from the incision. Located around the lancet opening 25, the compression surfaces 37, 38 have a first basin 39 and a second basin 40. The basins 39, 40 are angled to a greater degree than the outer radial sections of the compression surfaces 37, 38 so as to create a negative sigmoid shape. As mentioned above, the compression surfaces 37, 38 in the illustrated embodiment have a negative sigmoid shape so as to promote blood flow within the skin towards the incision. Together the compression surfaces 37, 38 and the basins 39, 40 form an expression area 41, which is illustrated in FIG.

2 as the area surrounded by dotted lines. In one embodiment, the relief notches 26 are sized and shaped so that generally only the expression area 41 of the expression surface 24 contacts the skin during expressing fluid. With the expression area 41 contacting the skin, blood flow in the arteries towards the incision is permitted; while at the same time pressure of the blood within the skin surrounding the incision can be increased. In another embodiment, the relief notches 26 are configured so that skin also contacts the expression surface 24 inside the relief notches 26.

In FIG. 2, the expression surface 24 is generally smooth, but it should be appreciated that the expression surface 24 can be textured in other embodiments. The expression surface 24 can be textured so as to promote expression of fluid from an incision by directing blood flow in the skin towards the incision. Moreover, the texturing of the expression surface 24 can increase friction between the skin and the expression surface 24, thus ensuring that the incision remains centered in the lancet opening 25. One example of texturing for an expression surface 24a is illustrated in FIG. 2A. As shown, the expression surface 24a incorporates ridges 42. The ridges 42 can be oriented in a number of manners to promote blood flow. The ridges 42 can be oriented to form concentric ring pattern, a spiral pattern as well as other patterns, for example. In other embodiments, the expression surface 24 can be covered with small spherical shapes, bumps, cones, rods, dimples, and/or other texturing.

With reference to FIGS. 3 and 4, the relief notches 26 in the illustrated embodiment are sized deeply enough to ensure that the skin surrounding the incision mainly contacts the compression surfaces 37, 38 when pressed against the expression surface 24. Nevertheless, the relief notches 26 in other embodiments are shallower so that the skin contacts the relief notches 26 and the compression surfaces 37, 38 at the same time, whereby the pressure exerted by the expression portion 21 is applied evenly around the incision. Opposite the expression surface 24, the expression portion 21 has a rim 45 that extends from the outer

periphery of the expression portion 21. In one embodiment, the rim 45 has an inside rim surface 49 that is used to frictionally secure the expression portion 21 to the support portion 22 of the cap 20. However, as mentioned before, it should be appreciated that the expression portion 21 can be secured to the support portion 22 in other manners and/or the expression portion 21 can be integrally formed with the support portion 22. In FIGS. 3 and 4, the compression surface 37 is depicted as gradually rising from the notches 26 to a top surface 47 that is generally flat when viewed on end. In other embodiments, the top surface 47 of compression surface 37 can be shaped differently. For instance, the top surface 47 in other embodiments can be saddle shaped such that the top surface 47 is curved with an apex located in its middle.

As depicted in FIG. 4, the compression surfaces 37, 38 have a negative sigmoid shape to enhance the expression of fluid from the incision. In the illustrated embodiment, the first 37 and second 38 compression surfaces respectively have first 51 and second 53 side ridges. At the side ridges 51, 53, the compression surfaces 37, 38 gradually taper to form the relief notches 33, 34. As noted of above, when expressing fluid from a finger or some other body part, the compression surfaces 37, 38 press on the sides of the finger so that blood moves within the skin towards the incision. In one form, the cap 20 does not contact the finger in the relief notches 26 when the cap 20 is pressed against the finger so as to promote fluid flow from the incision. It is envisioned that in other forms the cap 20 contacts finger in the relief notches 26

A bodily fluid sampling device 57, according to one embodiment, that incorporates the expression cap 20 is illustrated in FIG. 5. As shown, the sampling device 57 includes a body 59 and an incision forming device 61 for forming an incision in the skin. In the illustrated embodiment, the incision forming device 61 includes a lancet, but it is contemplated that the incision forming device 61 can include other types of devices, such as a

needle, laser, and/or a pneumatic needle, to name a few. The body 59 of the sampling device 57 is configured to actuate the incision forming device 61 to form the incision. Moreover, it should be appreciated that the body 59 in other embodiments can incorporate sensors for analyzing a fluid sample and a display for displaying the results of a test such that the sampling device is able to draw, collect and analyze a fluid sample in a single step.

The cap 20 is detachably secured to the body 59 to permit removal and replacement of the cap 20. To improve hygiene, the expression cap 20 in one embodiment is disposable; that is, the expression cap 20 is discarded and replaced with a new one after every test. It is contemplated that in other embodiments the cap 20 can be non-disposable such that it is removed and cleaned after every test. As shown in FIG. 6, the expression cap is attached to the support portion 22 at junction 63. In the illustrated embodiment, the expression cap 20 is secured to the body 59 via a tight interference fit, and the support portion 22 and the connection portion 23 are flexible to allow easy insertion and removal of the expression cap 20. However, other techniques of attaching the expression cap 20 to the body are contemplated. By way of a few nonlimiting examples, the cap 20 can be secured to the body 59 with adhesives, cooperating grooves or notches. In alternate embodiments, the expression cap 20 and the body 59 are permanently affixed to one another, and in still yet another embodiment, the cap 20 and the body 59 are coupled to one another in an adjustable manner to allow for variable lancing depths. To allow disposal, replacement and/or cleaning of the expression portion 21 of the cap 20, the expression portion 21 in one embodiment is detachably secured to the support portion 22 at junction 65 via a friction fit. However, in another embodiment, the expression portion 21 is permanently affixed to the support potion 22.

As depicted in FIG. 6, the incision forming device 61 includes a lancet 67 that that is coupled to a lancet driver 69. During lancing, the lancet driver 69 drives the lancet 67 into

the skin to form an incision. After forming the incision, the lancet driver 69 retracts the lancet from the incision. In one form, the lancet driver 69 includes springs for firing and retracting the lancet 67, and in another form, the lancet driver 69 includes an electric motor that is used to fire and retract the lancet 67. Nevertheless, it should be appreciated that the lancet driver 69 can incorporate other types of devices for firing and retracting the lancet 67. To reduce the risk of contamination, the lancet 67 can be discarded or cleaned after use.

A technique for collecting and analyzing body fluid with the sampling device 57 will now be described with reference to FIGS. 7, 8 and 9. Although the technique will be described with reference to collecting and analyzing a sample of blood, it should be appreciated that this technique can be used to collect and analyze other types of fluids, such as interstitial fluid. Before lancing, a finger 71 is placed in contact with the expression cap 20 such that a portion of the finger 71 is received in the relief notches 26. As shown in FIG. 9, the compression surfaces 37, 38 contact the sides of the finger 71. Once the finger 71 is in position, the lancet driver 69 fires the lancet 67 to form an incision in the finger 71, as is depicted in FIG. 7. As should be appreciated, the lancet driver 69 can be fired manually by the user or automatically by the device 57. Once the incision is formed, the lancet driver 69 retracts the lancet 67 from the finger 71 to allow blood flow from the incision.

After the incision is formed, a force F is applied by the cap 20 against the finger 71 to express fluid from the finger 71, as is illustrated in FIG. 8. The force F can be applied in a number of manners. For example, in one embodiment, the user presses the finger 71 against the expression cap 20 to express fluid. In another embodiment, the user manually presses the sampling device 57 against the finger 71 to express fluid, and in still yet another embodiment, the sampling device 57 automatically applies the force F against the finger 71. Nevertheless, it should be appreciated that the force F can be applied in other manners. In one embodiment, the surface area of the portion of the finger 71 that contacts the expression cap

20 is between about 0.2 to 0.6 square inches, and it was discovered that the size of this contact area enhances fluid flow from the incision. As the cap 20 is pressed against the finger, a bulge 73 on the finger 71 is created by the compressive forces applied by the compression surfaces 37, 38, and the blood is forced by the compression surfaces 37, 38 in direction A towards the incision. Body fluid 75 from the incision collects on the skin in the form of a drop.

In the illustrated embodiment, the body fluid 75 on the finger 71 is collected on test media 77 that disposed inside the expression 20. The test media 77 in the illustrated embodiment is in the form of a test strip that is used to analyze the body fluid 75. It is contemplated that the fluid 75 can be collected and analyzed in other manners. For example, the test media 77 can include an integrated lancing test strip in which the lancet 67 and the test strip 77 are configured as a unitary device that is able to lance the skin, sample the fluid and analyze the fluid sample. As should be appreciated, analyte levels can be determined through the chemical, electrical, electrochemical and/or optical properties of the bodily fluid sample collected on the test media, to name a few. For example, the test media 77 as illustrated is a chemically reactive reagent test strip. Typically, reagent test strips are sensitive to thermal and/or chemical processes required for sterilization. The sterilization process can effect the results generated by the test media 77, and therefore, recalibration of the test media 77 is required after sterilization. In the embodiment illustrated in FIG. 8, the lancet 67 can be separately sterilized when the expression cap 20 is removed. The test media 77 does not have to go through the same sterilization process as the lancet 67. After sterilization of the lancet 67, the expression cap 20 can be connected to the body 59, thereby eliminating the need to recalibrate the test media 77.

While the invention has been illustrated and described in detail in the drawings and foregoing description, the same is to be considered as illustrative and not restrictive in

character, it being understood that only the preferred embodiment has been shown and described and that all changes and modifications that come within the spirit of the invention are desired to be protected.